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# ABERDEEN PROVING GROUND ADVANCED PLANNING BRIEFING TO INDUSTRY

Joint Project Management Office for  
Medical Countermeasure Systems  
Presented by: COL Russell Coleman  
5 Nov 2015

*The forecast data is for planning purposes, does not represent a pre-solicitation synopsis, does not constitute an invitation for bid or request for proposal, and is not a commitment by the government to purchase the desired products and services*



# ABERDEEN PROVING GROUND ADVANCED PLANNING BRIEFING TO INDUSTRY

Joint Project Manager for Medical Countermeasure Systems  
Joint Vaccine Acquisition Program (JVAP)

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# PROGRAM OVERVIEW

Medical Countermeasures Systems (MCS) mission area is the development, production and fielding of medical solutions to counter Chemical, Biological, Radiological and Nuclear threats. Within MCS, the Joint Vaccine Acquisition Program (JVAP) has the mission to develop, produce and field FDA–licensed biological defense vaccines. Current JVAP portfolio includes vaccines for protection against Filoviruses, Equine Encephalitis viruses (western, eastern and Venezuelan) Botulinum Toxins (serotypes A and B), Ricin toxin and pneumonic Plague.

JVAP has a requirement for Engineering and Manufacturing Development of a filovirus vaccine that will protect against Ebola, Sudan, and Marburg through FDA approval (licensure).

JVAP intends to meet this requirement through a competitive contract award to a prime contractor.

- RFP release anticipated in late 2016
- Award anticipated in early 2017
- Period of performance expected to be through FDA approval
- Scope will include all manufacturing efforts, non-clinical studies and clinical trials required to support licensure/approval

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# OPPORTUNITY

**TITLE:** Trivalent Filovirus Vaccine

**CONTRACT TYPE:** CPIF/FFP CLINs

**ESTIMATED VALUE:** >\$300M

## CONTRACTING CONTACT:

ACC-APG

Mr. Lawrence Mize

301 619 9813

[lawrence.e.mize.civ@mail.mil](mailto:lawrence.e.mize.civ@mail.mil)

**SOLICITATION #:** TBD

**ESTIMATED SOLICITATION RELEASE DATE:**

Late 2016

\* The above opportunity will be considered for inclusion under the upcoming MCS OTA Consortium effort

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# ABERDEEN PROVING GROUND ADVANCED PLANNING BRIEFING TO INDUSTRY

Joint Project Manager for Medical Countermeasure Systems  
Biological Defense Therapeutics (BDTX)

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# PROGRAM OVERVIEW

JPM-MCS will award a Federal Acquisition Regulation (FAR) based contract to one or more performers. The primary indication of the base year award is to support development of a filovirus therapeutic medical countermeasure that is efficacious against at least one of the following Filoviruses: Zaire ebolavirus, Sudan ebolavirus, and Marburg marburgvirus.

BDTX will also provide a broad Statement of Objectives (SOO) for a forthcoming consortium Other Transactional Authority (OTA) solicitation, as well as for the MCS Broad Agency Announcement (BAA), for countermeasures efficacious against additional viral Biological Warfare Agents (BWAs). Additional viruses of interest include: Alphaviridae (Eastern Equine Encephalitis, Western Equine Encephalitis, Venezuelan Equine Encephalitis), Bunyaviridae (Hantaan), Filoviridae (Tai Forest, Bundibugyo).

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# OPPORTUNITY

**TITLE:** Antiviral Therapeutic RFP

**CONTRACT TYPE:** CPIF\*

**ESTIMATED VALUE:** \$160M - \$240M

## CONTRACTING CONTACT:

ACC-APG

Jessica Ely

301.619.8457

[jessica.l.ely.civ@mail.mil](mailto:jessica.l.ely.civ@mail.mil)

**SOLICITATION #:** W911QY-16-R-0002

**ESTIMATED SOLICITATION RELEASE DATE:** 1QFY16

\* The above opportunity will be considered for inclusion under the upcoming MCS OTA Consortium effort

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# OPPORTUNITY

**TITLE:** Antibacterial Therapeutic RFP

**CONTRACT TYPE:** CPIF\*

**ESTIMATED VALUE:** \$79-\$91M

**CONTRACTING CONTACT:**

ACC-APG

Sandra O'Connell

301.619.2895

[sandra.j.oconnell.civ@mail.mil](mailto:sandra.j.oconnell.civ@mail.mil)

**SOLICITATION #:** W911QY-15-R-0031

**ESTIMATED SOLICITATION RELEASE DATE:** TBD

\* The above opportunity will be considered for inclusion under the upcoming MCS OTA Consortium effort

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# ABERDEEN PROVING GROUND ADVANCED PLANNING BRIEFING TO INDUSTRY

Defense Threat Reduction Agency  
DTRA-CB-J9

Presented by: Dr. Erin Reichert  
5 Nov 2015

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# DTRA J9-CBM – TRANSLATIONAL MEDICINE OVERVIEW

Vision: Develop vaccines and therapeutics to mitigate the threat of biological warfare agents

## Focus Areas

- Bio-Therapeutics Branch
  - Discovery and development of therapeutics for alphaviruses, filoviruses, botulinum toxin, and broad-spectrum antibiotics targeting multi-drug resistant bacterial threat pathogens
- Bio-Pretreatments Branch
  - Discovery and development of vaccines for: alphaviruses, filoviruses, *Bacillus anthracis* (anthrax), *Burkholderia mallei* (glanders), *Burkholderia pseudomallei* (melioidosis), *Francisella tularensis* (tularemia), *Coxiella burnetii* (Q Fever), and botulinum, ricin, and SEB toxin
- Supporting S&T
  - Investments in animal model development, ex vivo human mimetics, novel manufacturing technologies that exploit readily adaptable expression platforms and leverage flexible biomanufacturing technologies, understanding host-pathogen/toxin interaction for identification of targets and/or biomarkers, adjuvants and stabilization technologies, drug delivery methods, and compound library compilation and characterization

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# OPPORTUNITY

## TITLE:

- **CBM-01 Late Discovery and Development of Novel Therapeutic Approaches to Combat Antimicrobial Resistance in Biological Threat Agents**

## GOAL:

- **Development of novel antimicrobial agents that will potently treat multiple drug resistant bacteria especially those considered priority threat agents by the DoD**

## CONTRACTING CONTACT:

Lindsay Odell, PhD  
DTRA J9CBM  
lindsay.t.odell.civ@mail.mil

**SOLICITATION #: HDTRA1-14-CHEM-BIO-BAA Amd #3**

**ESTIMATED SOLICITATION RELEASE DATE: Sept 28, 2015**

**Specific questions about open solicitation topics should be sent to:**

**dtra.belvoir.J9.mbx.CB-FY14-16-BAA@mail.mil**

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# OPPORTUNITY

## TITLE:

- **CBM-02 Advanced Bacterial Antimicrobial and Anti-Infective with Novel Mechanisms of Action**

## GOAL:

- **Development of novel antimicrobial agents that will potently treat multiple drug resistant bacteria especially those considered priority threat agents by the DoD and which have mechanisms of action distinctly unique relative to marketed antimicrobial drugs.**

## CONTRACTING CONTACT:

Lindsay Odell, PhD  
DTRA J9CBM  
[lindsay.t.odell.civ@mail.mil](mailto:lindsay.t.odell.civ@mail.mil)

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# OPPORTUNITY

## TITLE:

- **CBM-03 Novel Small Molecule Medical Countermeasures Development Targeting Filoviridae Pathogenesis and Resistance**

## GOAL:

- **Development of novel and innovative small molecules that have the potential to be used as post-exposure prophylactics or therapeutics against one or both Filovirus family members (Marburg and Ebola) and any combination of the five Ebola species (Tai Forest, Sudan, Zaire, Reston or Bundibugyo).**

## CONTRACTING CONTACT:

Lindsay Odell, PhD  
DTRA J9CBM  
[lindsay.t.odell.civ@mail.mil](mailto:lindsay.t.odell.civ@mail.mil)

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# OPPORTUNITY

## TITLE:

- **CBM-04 Animal Model Development for Evaluation of Therapeutic Medical Countermeasures**

## GOAL:

- **Animal models that provide both longitudinal study and aerosol challenge capabilities. These models should be robust and able to define the natural history of the disease as well as the ability to determine biomarkers that can be used in diagnosing and/or treatment. These models must be acceptable by the FDA for approval of therapeutics by the Animal Rule**

## CONTRACTING CONTACT:

**Lindsay Odell, PhD  
DTRA J9CBM  
lindsay.t.odell.civ@mail.mil**

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# OPPORTUNITY

## TITLE:

- **CBMV-01 Investigation of Next-Generation Nucleic Acid Vaccine Platforms**

## Major Goal:

- **Use a mature DTRA-funded VEE DNA vaccine candidate, as the baseline to assess the feasibility of promising next-generation nucleic acid platforms and nucleic acid formulations for rapid production of effective pretreatments.**

## CONTRACTING CONTACT:

**Dr. David Hone,  
DTRA J9CBMV, Pretreatments  
david.m.hone2.civ@mail.mil**

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# OPPORTUNITY

## TITLE:

- CBMV-02 Medical Countermeasures for Western, Eastern and Venezuelan Encephalitis Virus: *Mucosal Vaccine Development and Identification of Markers of Infection in Animal Models*

## Major Goal:

- Vaccine development that will protect against Western, Eastern and Venezuelan equine encephalitis viruses and that can be delivered via mucosal routes, including intranasal, sublingual, or buccal.

## CONTRACTING CONTACT:

Dr. David Hone,  
DTRA J9CBMV, Pretreatments  
david.m.hone2.civ@mail.mil

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# OPPORTUNITY

## TITLE:

- **CBMV-03 Vaccines Directed Against Burkholderia Species**

## Major Goal:

- Solicitation for melioidosis and/or glanders vaccines that show sufficient efficacy and acceptable safety profiles in relevant animal models.

## CONTRACTING CONTACT:

Dr. David Hone,  
DTRA J9CBMV, Pretreatments  
david.m.hone2.civ@mail.mil

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# OPPORTUNITY

## TITLE:

- **CBMV-04 Broad Spectrum Prophylaxis of Biological Toxins**

## Major Goal:

- **Development of prophylactic MCMs applicable to a broad range of biotoxins of diverse taxonomic origins.**

## CONTRACTING CONTACT:

Dr. David Hone,  
DTRA J9CBMV, Pretreatments  
[david.m.hone2.civ@mail.mil](mailto:david.m.hone2.civ@mail.mil)

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# OPPORTUNITY

## TITLE:

- CBMV-05 Development of an Animal Model with Pre-Existing Immunity to *Coxiella Burnetii*

## Major Goal:

- Development and standardization of an animal model for assessing vaccine-related adverse reactions that are similar to those observed in humans.

## CONTRACTING CONTACT:

Dr. David Hone,  
DTRA J9CBMV, Pretreatments  
david.m.hone2.civ@mail.mil

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# ABERDEEN PROVING GROUND ADVANCED PLANNING BRIEFING TO INDUSTRY

Joint Project Manager for Medical Countermeasure Systems  
Chemical Defense Pharmaceuticals (CDP)

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# PROGRAM OVERVIEW

## Improved Nerve Agent Treatment System (INATS)

- Family of Systems to provide FDA-approved improved oxime to be used in conjunction with Atropine in a combined autoinjector delivery system
  - Improved Oxime Treatment Increment
    - To replace 2-PAM in the currently fielded ATNAA, for a broad spectrum of traditional nerve agents and emerging threats
  - Expanded Indication for Pyridostigmine Bromide (PB) Increment
    - Complementary to Improved Oxime Treatment Increment
    - FDA approval for use beyond Soman; for additional traditional nerve agents and emerging threats
  - Increased Survival Increment
    - Complementary adjunct to Improved Oxime Treatment Increment
    - A centrally-acting (CA) therapeutic to increase survival

## Expansion of Autoinjector Manufacturing Base

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# OPPORTUNITY

**TITLE:** Improved Nerve Agent Treatment System (INATS),  
Improved Oxime Treatment Increment

**CONTRACT TYPE:** Full and Open, Multiple Award FAR part 15  
including CPFF, CPIF and FFP CLINS\*

**ESTIMATED VALUE:** \$40M-\$60M

**CONTRACTING CONTACT:** TBD

**SOLICITATION #:** TBD

**ESTIMATED SOLICITATION RELEASE DATE:** 4QFY16 –  
3QFY17

\* The above opportunity will be considered for inclusion under the  
upcoming MCS OTA Consortium effort

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# OPPORTUNITY

**TITLE:** Expansion of Autoinjector Manufacturing Base

**CONTRACT TYPE:** Full and Open, Multiple Award FAR part 15 including CPFF, CPIF and FFP CLINS\*

**ESTIMATED VALUE:** TBD

**CONTRACTING CONTACT:** TBD

**SOLICITATION #:** TBD

**ESTIMATED SOLICITATION RELEASE DATE:** 4QFY16 – 2QFY17

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# ABERDEEN PROVING GROUND ADVANCED PLANNING BRIEFING TO INDUSTRY

Defense Threat Reduction Agency  
DTRA-CB-J9

Presented by: Dr. Eric Moore  
5 Nov 2015

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# DTRA J9CBS – ADVANCED AND EMERGING THREAT OVERVIEW

**Mission:** Develop and transition novel concepts and technologies to address current and emerging chemical threats to protect the lives of our warfighters

## Objectives:

- Provide rapid validated chemical and biological agent property and reactivity data and determine toxicological mechanisms to inform risk assessment.
- Deliver novel medical concepts and technologies (i.e. pretreatments & therapeutics) to address current and emerging chemical threats to protect the lives of our warfighters.
- Provide capabilities and competency to the DoD labs through the DTRA Fellowship program, explore collaborative opportunities, and recruit and mentor young talent through scholarly programs (e.g. STEM and Post-doctoral).

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# OPPORTUNITY

## TITLE:

- **CBS-01 Organophosphorus Nerve Agent Medical Countermeasures**

## GOAL:

- **Improved and/or enhanced prophylaxis or therapeutics MCMs to augment the standard treatment regimen for chemical warfare agents (CWA) intoxication. The aim of this optimization is increased survival, reduced morbidity, and decreased neurological adverse effects for emergency use/acute treatment of CWA intoxication.**

## CONTRACTING CONTACT:

**LCDR Ayodele Olabisi, PhD  
DTRA J9CBS  
ayodele.o.olabisi.mil@mail.mil**

**SOLICITATION #: HDTRA1-14-CHEM-BIO-BAA Amd #3**

**ESTIMATED SOLICITATION RELEASE DATE: Sept 28, 2015**

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**dtra.belvoir.J9.mbx.CB-FY14-16-BAA@mail.mil**

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# ABERDEEN PROVING GROUND ADVANCED PLANNING BRIEFING TO INDUSTRY

Joint Project Manager for Medical Countermeasure Systems  
Diagnostics (DX)

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# PROGRAM OVERVIEW

Next Generation Diagnostics System Increment 2 (NGDS Inc 2) will provide a set of affordable and supportable materiel solutions to address CBRN diagnostics

NGDS Inc 2 is part of a Family of Systems approach

- Seeking complementary diagnostic capability with NGDS Inc 1 PCR analyzer (FilmArray)
- Near term mature solutions for CBRN diagnostics that would add value to treatment decisions
- Considering platform development effort that could address a broad range of CBRN threats and diagnostic approaches, to include host response biomarkers

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# OPPORTUNITY

**TITLE:** Next Generation Diagnostics System Increment 2  
Platform Component Development

**CONTRACT TYPE:** FFP/CPFF\*

**ESTIMATED VALUE:** \$40M-\$60M

**CONTRACTING CONTACT:**

ACC-Natick Jessica Ely  
301-619-8457

[Jessica.l.ely.civ@mail.mil](mailto:Jessica.l.ely.civ@mail.mil)

**SOLICITATION #:** TBD

**ESTIMATED SOLICITATION RELEASE DATE:** Draft release  
2QFY16

\* The above opportunity will be considered for inclusion under  
the upcoming MCS OTA Consortium effort

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Defense Threat Reduction Agency  
DTRA-CB-J9

Presented by: Dr. Rich Schoske  
5 Nov 2015

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# DTRA J9CBA – DIAGNOSTICS, DETECTION AND DISEASE SURVEILLANCE OVERVIEW

Vision: Comprehensive early warning to reduce biological and chemical threats

## Focus Areas

- Assays and Biomarkers
  - Development and verification of rapid, sensitive, and specific tests for the identification of Chemical Biological Warfare Agents (CBWAs)
  - Discovery of host biomarkers generated in response to exposure to biological threat agents
- Detection and Diagnostic Systems Development
  - Detection and identification of chemical and biological threats in near real-time
  - Diagnostic device development to include systems able to harness next generation technologies to revolutionize clinical diagnostics in care facilities and in hospital laboratories
  - Future programs focus on the improvement of algorithms, excitation sources, and detector elements to increase warning time, reduce false positives, increase sensitivity, and reduce cost
- Disease Surveillance
  - Development of a biosurveillance framework and integration and demonstration of standards-based device-to-cloud connectivity
  - Development and testing of Buddy-care devices and Role 1 diagnostic device solutions with capability of data upload
  - Next generation analytic capabilities for prediction, early warning and forecasting.

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# OPPORTUNITY

## TITLE:

- **CBA-01 In Situ Protein and Gene Expression Platform Technologies for Host Response Biomarker Methods and Analysis**

## CONTRACTING CONTACT:

Lt Col David Watson,  
DTRA J9CBA Assays and Biomarkers  
david.g.watson22.mil@mail.mil

**SOLICITATION #: HDTRA1-14-CHEM-BIO-BAA Amd #3**

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# OPPORTUNITY

## TITLE:

- CBA-02 Ultra-Rapid, Low Power Multiplexed PCR-based Molecular Diagnostics Point-of-Care Devices
- CBA-03 Pre-Analytical Method Refinement: Novel Bio-Sample Collection, Preservation, and Preparation
- CBA-04 Discovery of Proteomic Signatures to Distinguish Pathogen Growth Conditions
- CBA-05 Personal Chemical Hazard Detector

## CONTRACTING CONTACT:

Dr. Brandi Vann,  
DTRA J9CBA Diagnostic & Detection Systems Development  
[brandi.c.vann.civ@mail.mil](mailto:brandi.c.vann.civ@mail.mil)

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# OPPORTUNITY

## TITLE:

- CBA-06 New Analytics and Data Sources to Support Global DoD Biosurveillance
- CBA-07 Making Disease Forecasts Actionable: Novel displays, Uncertainty Quantification and Ensemble Approaches
- CBA-08 Field Forward Diagnostics
- CBA-09 Predicting Disease (Re)Emergence
- CBA-10 Evaluation of Wearable Technologies for Early Indication of Health Changes
- CBA-11 Can Social Media Data Predict the Future?

## CONTRACTING CONTACT:

Dr. John Hannan,  
DTRA J9CBA Disease Surveillance  
[john.r.hannan2.civ@mail.mil](mailto:john.r.hannan2.civ@mail.mil)

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